117TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods.

IN THE SENATE OF THE UNITED STATES

Mr. CASEY (for himself, Mr. BROWN, Ms. DUCKWORTH, Mrs. GILLIBRAND, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent food shortages, including shortages of infant formula and certain medical foods.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Protecting Infants from Formula Shortages Act of 2022''.

SEC. 2. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF ESSENTIAL SOURCES OF NUTRITION.

(a) DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF ESSENTIAL FOOD.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 412 (21 U.S.C. 350a) the following new section:

"SEC. 412A. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF FOOD, INCLUDING INFANT FORMULA AND CERTAIN MEDICAL FOODS FOR INBORN ERRORS OF METABOLISM.

''(a) IN GENERAL.—A manufacturer of an essential source of nutrition shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of such food or an interruption of the manufacture of an essential source of nutrition or any other circumstance that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption.

''(b) TIMING.—Except as provided in subsection (g), a notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute, to the Secretary of Agriculture and to appropriate organizations, as determined by the Secretary, through such means as the Secretary determines appropriate, information on the discontinuance or interruption of the manufacture of an essential source of nutrition, or other circumstance, reported under subsection (a).

''(d) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

''(e) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

''(1) the Secretary shall issue to such person a letter that—

''(A) informs such person of the failure to comply;

''(B) describes the basis for noncompliance; and

''(C) requires the person to comply not later than 30 calendar days after the date on which the letter was issued;

''(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter that provides the information required under subsection (a); and

''(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the website of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

''(f) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Protecting Infants from Formula Shortages Act of 2022, the Secretary shall promulgate regulations regarding the requirements under this section.

''(2) CONTENTS.—Such regulations—

"(A) shall include a list of each category of food for which a manufacturer is required to notify the Secretary in accordance with subsection (a); and

"(B) may—

"(i) designate foods not otherwise defined as an essential source of nutrition, giving special consideration to foods—

"(I) upon which individuals with certain diseases or conditions may be particularly reliant; or

"(II) that are administered under medical supervision;

"(ii) designate additional categories of foods for which the Secretary determines notification described in subsection (a) is appropriate during a public health emergency declared under section 319 of the Public Health Service Act; and

"(iii) prescribe additional conditions on the timing and manner of such notifications as are reasonable and appropriate during such a public health emergency.

"(g) ORDER.—During a public health emergency declared under section 319 of the Public Health Service Act,

the Secretary may order any manufacturer of an essential source of nutrition to provide notification required by this section. Such order may—

''(1) impose additional conditions on the timing and manner of notification as are reasonable and appropriate in light of the circumstances of the public health emergency; and

''(2) designate additional categories of food for which the Secretary determines notification is appropriate during the public health emergency.

''(h) RISK MANAGEMENT PLANS.—Each manufacturer of an essential source of nutrition shall develop, maintain, and, as appropriate, implement a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured. A risk management plan under this subsection—

''(1) may identify and evaluate risks to the supply of more than one food, or food category, manufactured at the same establishment; and

''(2) shall be subject to inspection and copying by the Secretary pursuant to section 704 or at the request of the Secretary.

''(i) DEFINITIONS.—In this section:

''(1) ESSENTIAL SOURCE OF NUTRITION.—The term 'essential source of nutrition' means—

''(A) an infant formula;

''(B) a food that—

''(i) meets the definition of 'medical food' in section 5(b) of the Orphan Drug Act; and

''(ii) is intended for use by individuals with—

''(I) certain inborn errors of metabolism; or

''(II) other conditions requiring a medical food, as determined by the Secretary in guidance issued under subsection (f); or

''(C) a food so designated pursuant to subsection (f).

''(2) MEANINGFUL DISRUPTION.—The term 'meaningful disruption'—

''(A) means a change in production that is reasonably likely to lead to a reduction in the supply of an essential source of nutrition by a manufacturer that is more than negligible and affects the ability of the manufacturer to fulfill

contractual obligations or meet expected demand for its product; and

''(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following new subsection:

''(fff) The failure to provide information as required under section 412A after receipt of a letter from the Secretary under subsection (e) of such section.''.

SEC. 3. REMOTE RECORDS ASSESSMENT FOR ESSENTIAL SOURCES OF NUTRITION.

(a) FACTORY INSPECTION.—Section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)(A)) is amended in the first sentence by inserting ''or the manufacturing, processing, packing, or holding of an essential source of nutrition (as defined in section 412A)'' after ''processing of a drug''.

(b) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Sec-

retary'') shall promulgate regulations describing circumstances in which the Secretary may issue requests for records or other information in advance of, or in lieu of, an inspection pursuant to section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a), processes for responding to such requests electronically or in physical form, and factors the Secretary may consider in evaluating whether such records are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses.